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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/600,871  | 06/20/2003  | R. Glen Coleman      | PD-170.02            | 6659             |
| 27581   | 7590        | 03/11/2005           | EXAMINER             |                  |
| MEDTRONIC, INC.<br>710 MEDTRONIC PARKWAY NE<br>MS-LC340<br>MINNEAPOLIS, MN 55432-5604 |             |                      | SULLIVAN, JULIANNE M |                  |
|   |             | ART UNIT             | PAPER NUMBER         |                  |
|   |             |                      | 3737                 |                  |

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/600,871             | COLEMAN, R. GLEN    |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Julianne M. Sullivan   | 3737                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 December 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to Claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.
2. With respect to Applicant's arguments regarding the rejection of Claims 1-3, 9-12, 14 and 15 as obvious over Anderson et al. (U.S. Patent No. 4,562,900) in view of Iinuma (U.S. Patent No. 5,448,994), the Examiner has introduced a new reference, Klopotek (U.S. Patent No. 6,113,559), to meet the limitations added to the Claims. Klopotek expressly discloses an ultrasound system having distinct foci, as discussed in the rejection below.

In response to Applicant's argument that modification of Anderson et al. and Iinuma to include this feature would destroy the intent, purpose or function of the inventions, the Examiner argues that the use of a system as in Klopotek providing multiple foci for the ultrasound device is consistent with the teachings of Anderson et al. and Iinuma, even though it was not explicitly disclosed. Anderson et al. recites that the purpose of its device is to "direct and focus acoustic energy into a small target," (col. 1, lines 11-12). This purpose does not state or imply a preference for a single focal point. Moreover, providing duplication of parts to achieve multiple effects is a well-known technique. See, e.g., *In re Harza*, 274 F.2d 669, 671, 124 USPQ 378, 380 (CCPA 1960) (holding that mere duplication of ribs in a water seal has no patentable significance without a new and unexpected result).

Here, Anderson et al. discloses a group of transducer elements that focus in one place (see Fig. 2). The related reference, Klopotek, discloses a similar group of elements further gathered in a larger number to form a series of groups, each group having a focus (see col. 4,

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lines 4-8 and 10-11 and Fig. 2). However, Klopotek also states that *either* “a single curved transducer or multiple transducer elements could be used in the transducer,” (col. 4, lines 8-10), thus if a single curved transducer were used, each transducer along the series would have its own focus. Therefore, Klopotek can be used to modify Anderson et al. to merely duplicate the elements of Anderson et al. to achieve multiple foci and to replace the several elements corresponding to each focus with a single curved element. The Applicant has suggested no new or unexpected result; rather, the result is merely ablation of tissue at the multiple focal points instead of at a single point. Neither the teachings of Anderson et al., nor of Iinuma preclude such duplication of parts or substitution of one curved element for several elements, and as discussed in the rejection below, it would have been obvious to use an ultrasound device having multiple foci; therefore Claims 1-3, 9-12, 14 and 15 are rejected below.

3. With respect to Applicant’s arguments regarding the rejection of Claims 4, 6-8, 13, 16 and 18-20 as obvious over Anderson et al. in view of Iinuma, and further in view of Castel (U.S. Patent No. 5,413,550), and the rejection of Claims 5 and 17 as obvious over Anderson et al. in view of Iinuma, and further in view of Weng et al. (U.S. Patent No. 6,626,855), the Examiner has introduced a new reference, Klopotek, as discussed above, to meet the limitations added to Claims 1 and 9. Accordingly, dependent Claims 4-8, 13 and 16-20 remain rejected as obvious over the combinations of the references provided.

4. With respect to Applicant’s arguments regarding the rejection of Claims 21-27 as obvious over Anderson et al. in view of Castel, the Examiner has introduced a new reference, Klopotek, to meet the limitations added to the Claims. Klopotek teaches an ultrasound system having distinct foci, where each focus may correspond to a single emitting element, as discussed above

with respect to Claims 1 and 9. As such, the step of focusing the ultrasound energy as described in Claim 21 is met by Anderson et al. in view of Klopotek. Additionally, the remaining steps of the methods of Claims 21-27 are met by Anderson et al. in view of Castel, and further in view of Klopotek, as discussed below; therefore, Claims 21-27 remain rejected.

***Specification***

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The abstract of the disclosure is objected to because it exceeds the 150-word limit.

Appropriate correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 9-12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (U.S. Patent No. 4,562,900) in view of Iinuma (U.S. Patent No. 5,448,994), and further in view of Klopotek (U.S. Patent No. 6,113,559).

With regard to the rejected claims, Anderson et al. discloses an apparatus and method of providing a lightweight, single-piece tray of properly aligned transducer/lens elements for use in the usual treatment or diagnostic environment devices to simplify the procedures and improve the quality of treatment delivered to the patient. Figures 1 and 2 of Anderson et al. diagram the system. An array of transducers and lenses (ref. nos. 14 and 12, respectively) is positioned in a generally rectangular tray (ref. no. 10) to provide for the focused ultrasound heat treatment (col. 1, lines 11-13). With regard to Claims 1 and 9, Figures 1 and 2 of Anderson et al. diagram ultrasound emitting members (ref. nos. 14 and 12) spaced from one another along a row, such that ultrasound is emitted at a predetermined distance outwardly from an active surface. With respect to Claim 1, the Examiner interprets an active surface as the surface from which the ultrasound waves are emitted; accordingly, this surface is inherent in any ultrasound wave-propagating device. With respect to Claim 9, the active surface is interpreted as carrying one or more rows of spaced-apart ultrasound-emitting elements. Accordingly, the holding frame for housing the tray of the transducer/lens assembly as taught by Anderson et al. satisfies the active surface limitation of Applicant's Claim 9 (col. 1, lines 64-66).

With respect to Claims 2, 10 and 14, the transducer elements of Anderson et al. satisfy the piezoelectric elements of the applicant by emitting ultrasound energy in response to an electric current supplied. With respect to Claims 3 and 15, although Anderson et al. does not teach a curved transducer element, the transducer/lens assembly of Anderson et al. satisfies the

function of providing a focused ultrasound treatment. Therefore, it would have been obvious to provide either the curved transducer element or the transducer/lens assembly because they are functional equivalents.

Regarding the claims generally, Anderson et al. does not explicitly recite a handle. More specifically to Claims 11 and 12, Anderson et al. does not disclose the power supply and the control unit, respectively. Furthermore, Anderson et al. does not teach selective actuation and de-actuation of the one or more transducer elements. It is inherent or in the alternative obvious to one of ordinary skill in the art at the time the invention was made to provide for a handle such that maneuverability of the device is possible. A common definition of a handle is an appendage to an object such that the object can be moved or used. According to this definition, a handle is inherent or in the alternative obvious such that the lightweight single piece tray of transducer/lens elements can be moved or used to provide the appropriate ultrasound treatment to the tissue.

Further, it is inherent or in the alternative obvious to one of ordinary skill in the art at the time the invention was made to provide a power supply for generating an electric signal to actuate the elements, thereby emitting ultrasound, because a power supply is necessary for the functionality of the device. The treatment cannot be performed without the necessary power source. Iinuma teaches a system and method of ultrasound therapy comprising a control unit for selective actuation and de-actuation of the transducer elements to provide treatment to desired regions (col. 6, lines 28-37). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Iinuma with the teachings of Anderson

et al., thus satisfying the Applicant's invention because it allows for better control of the therapy procedure to the desired area of the tissue as taught by Iinuma.

With respect to Claims 1 and 9, Anderson et al. does not explicitly teach that the ultrasound energy is focused at separate and distinct locations for each element. In the same field of endeavor, Klopotek discloses an ultrasound system having distinct foci, where the foci may be continuous with each other or discontinuous (col. 3, lines 5-7, 15-18 and 21-22, col. 4, lines 4-20, col. 7, lines 7-15 and Figs. 8 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the multi-foci apparatus of Klopotek in a hand-held ultrasound device in order to deliver ultrasound to a patient in a specific pattern of locations within the body.

9. Claims 4, 6-8, 13, 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Iinuma, and further in view of Klopotek as applied to Claims 1 and 9 above, and further in view of Castel (U.S. Patent No. 5,413,550).

Anderson et al. in view of Iinuma and Klopotek discloses the claimed invention as discussed above except for the specifics of the handle of the ultrasound therapeutic device. Figure 2 of Castel diagrams the specifics of the handle as disclosed in Applicant's claims. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the present invention via the combination of the hand-held ultrasonic applicator with the control features of Castel because the graspable handle with control switches or buttons allows for quicker and thus better control of the therapeutic procedure, which is a well known expedient in the art.

10. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Iinuma, and further in view of Klopotek as applied to Claims 1 and 9 above, and further in view of Weng et al. (U.S. Patent No. 6,626,855).

Anderson et al. in view of Iinuma teaches the present claimed invention as discussed above except for the malleability of the handle shaft of the ultrasound therapeutic device. Figure 3C of Weng et al. diagrams the flexible portion (ref. no. 31) of the handle shaft. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the present invention via the combination of the held-held ultrasonic applicator with the flexible handle shaft of Weng et al. because the flexibility or malleability of the handle shaft allows for better maneuverability of the device to different regions of interest as taught by Weng et al. (see col. 10, lines 43-49).

11. Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Castel, and further in view of Klopotek.

With respect to Claim 21, Anderson et al. teaches a method of ultrasound treatment of a tissue by heating the tissue. The lightweight tray of Anderson et al. holds an array of transducer/lens elements to be positioned adjacent to the tissue of a patient. The transducers are actuated to provided focused ultrasound energy at a predetermined distance from the active surface, as shown in Figure 2 of Anderson et al. The step of providing ultrasound treatment via the entire tray of transducer/lens elements of Anderson et al. satisfies Applicant's limitation to selecting and actuating one or more ultrasound emitting elements.

With respect to Claims 22 and 23, although Anderson et al. does not explicitly recite the step of providing an electric current to actuate the transducer elements, it is inherent or in the

alternative obvious to one of ordinary skill in the art at the time the invention was made to provide the step of an electric signal to actuate the elements, thereby emitting ultrasound, because this step is necessary for the method to be performed. The treatment cannot be performed without the necessary electric signal. Furthermore, with respect to Claims 24-26, Anderson et al. does not explicitly recite the desired dimensions or pattern of the tissue to be heat-treated. However, in the same field of endeavor, Klopotek expressly teaches an ultrasound system having distinct foci, where the foci may be continuous with each other or discontinuous (col. 3, lines 5-7, 15-18 and 21-22, col. 4, lines 4-20, col. 7, lines 7-15 and Figs. 8 and 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the multi-foci apparatus of Klopotek in a hand-held ultrasound device in order to select specific delivery patterns of ultrasound to tissue within the body of a patient.

In addition, although the term “ablation” of tissue is not present in the Anderson et al. reference, the teaching to “heat the target” includes or makes obvious ablation of the tissue. It would have been obvious for one of ordinary skill in the art at the time the invention was made to ablate the target tissue because the method of Anderson et al. does not preclude one from tissue ablation since the patent discloses ultrasound heating of the target.

Finally, the step of grasping a handle coupled to the ultrasound-emitting member is not expressly taught in the Anderson et al. reference. The step of grasping would have been inherent such that the lightweight tray of the transducer/lens assembly of Anderson et al. can be positioned adjacent to the target tissue. Or, in the alternative, the step of grasping is obvious in view of Castel. Figure 2 of Castel diagrams the step of grasping such that the handle is external to the patient. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to combine the methods of Anderson et al. and Klopotek with the method of Castel because the step of grasping the handle allows for maneuverability of the lightweight tray assembly of Anderson et al.

*Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianne M. Sullivan whose telephone number is 571-272-6084. The examiner can normally be reached on Monday through Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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